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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/697,444	10/29/2003	Joseph J. Spranza	SDEV-1-1003	7974
25315 7590 05/05/2010 BLACK LOWE & GRAHAM, PLLC 701 FIFTH AVENUE SUITE 4800 SEATTLE, WA 98104				
EXAMINER KOHARSKI, CHRISTOPHER				
ART UNIT		PAPER NUMBER		
3763				
NOTIFICATION DATE		DELIVERY MODE		
05/05/2010		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/697,444

Applicant(s)

SPRANZA ET AL.

Examiner

CHRISTOPHER D. KOHARSKI

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 February 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-51 is/are pending in the application.
- 4a) Of the above claim(s) 46-51 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27-33 is/are rejected.
- 7) ☒ Claim(s) 34-45 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10/29/2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-06)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION***Acknowledgements***

The Examiner acknowledges the reply filed 02/16/2010 in which claims 27-51 are pending for examination in this application. Additionally, the Examiner also acknowledges the request for a non-final action.

Election/Restrictions

Claims 46-51 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 02/16/2010. Applicant's election with traverse of the group election in the reply filed on 02/16/2010 is acknowledged. The traversal is on the ground(s) that the device of Group I cannot be used to perform a materially different task as recited. This is not found persuasive because the device can be re-used without resetting the safety mechanism, or the device can be used without actuation of the lockable safety sheath.

The requirement is still deemed proper and is therefore made FINAL.

112 6th Acknowledgement

With regard to Applicant's "means for connecting a tube thereto" of claim 27, the language appears to be an attempt to invoke 35 USC 112, 6th paragraph interpretation of the claims. A claim limitation will be interpreted to invoke 35 U.S.C. 112, sixth paragraph, if it meets the following 3-prong analysis:

- (A) the claim limitations must use the phrase "means for" or "step for;"

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(B) the "means for" or "step for" must be modified by functional language;

and

(C) the phrase "means for" or "step for" must not be modified by sufficient structure, material or acts for achieving the specified function.

In the instant case, applicant appears to have met the limitations set forth in MPEP § 2181, and examiner has turned to the specification for clarification.

In the specification, applicant defines the "means for connecting a tube thereto" as a barb or connection fitting. Accordingly, the examiner is interpreting the "means for connecting" to encompass barb tubing connectors and its equivalents. Equivalent structures may include those that perform the function specified in the claim, structures that are not excluded by any specific definition provided in the specification for an equivalent, or is a structural equivalent of the corresponding element disclosed in the specification. See MPEP 2183.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 27 and 30-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Brimhall et al. (USPN6,004,294). Brimhall et al. discloses a catheter and introducer needle assembly with needle shield.

Regarding claims 27 and 30-32, Brimhall et al. discloses a sharp instrument and sheath (Figure 1), comprising: an elongate rod (32) having first and second ends, the first end having a sharp point (near 32) and an upper portion (near 33) defining a first longitudinal axis and the second end having means for connecting a tube thereto (luer lock 36), wherein the second end includes a recess (near 37) configured to receive an indexing means of a safety guide for rotationally orienting the elongate rod with respect to the first longitudinal axis; and a selectively and longitudinally lockable safety sheath (40) for receiving the first end (near 32) of the rod (Figure 3), and wherein when the sheath is locked onto the first end of the elongate rod (Figure 5), the sheath (40) is sufficiently elongated so as to substantially cover the sharp point (Figure 5), and wherein the sheath has a locking device (55) configured to selectively grip a shaft of the sharp instrument, holding the sharp pointed end within, and wherein the selectively lockable safety sheath includes an annular locking vane (50) defining a circular aperture (Figure 6, near 51) adapted to receive the first end of the sharp instrument in a first unlocked position and movable to a second locked position (Figures 1-6).

Claim Rejections - 35 USC § 102

Claim 33 is rejected under 35 U.S.C. 102(b) as being anticipated by Yoon (USPN5,779,680). Yoon discloses a retractable safety needle instrument with movable safety member.

Regarding claim 33, Yoon discloses a sharp instrument and a safety guide (Figure 1) for placing the sharp instrument through the skin of a patient (cols 1-2), comprising: a sharp instrument (36); a first end of a safety guide (near 76) having a receiver mechanism (open end of tube) adapted for lockably (via 108) accepting a sharp point (near 64, Figure 3) of the sharp instrument (36); a second end (near 110) of a safety guide having a holder mechanism (housing 46) adapted for releasably securing the sharp instrument in all directions (via 108); and a guide beam (26) having a linear elongated body and a substantially uniform cross-section along its length, wherein the receiver mechanism and the holder mechanism are guided in continuous linear alignment along at least a portion of the guide beam (26) such that the sharp point of the sharp instrument follows a substantially straight line from within the receiver mechanism to a position apart from the receiver mechanism and back into the receiver mechanism when the safety guide is actuated (Figures 1-3).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which

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said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 31 is rejected under 35 U.S.C 103(a) as being unpatentable over Brimhall et al. (USPN6,004,294) in view of Pyles (USPN5,669,882). Brimhall et al. meets the claim limitations as described above except for a bent needle.

However, Pyles teaches a curved needle system.

Regarding claim 31, Pyles teaches a curved sharp instrument (30) that has an offset portion (near 16, Figures 1-2).

At the time of the invention, it would have been obvious to incorporate the needle curve of Pyles to the system of Brimhall et al. in order to allow for greater access to specific parts of the body and increase ease of insertion. The references are analogous in the art and with the instant invention; therefore, a combination is proper. Therefore, one skilled in the art would have combined the teachings in the references in light of the disclosure of Pyles (cols 1-2).

Allowable Subject Matter

Claims 34-45 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher D. Koharski whose telephone number is 571-272-7230. The examiner can normally be reached on 5:30am to 2:00pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Date: 04/29/2010

/Christopher D Koharski/
Examiner, Art Unit 3763